REMARKS

Upon entry of the amendments herein, claims 1-4, 6 and 7 are pending in the application. Claims 1-4 and 6 have been amended; claim 5 has been canceled; and new claim 7 has been added. No new matter has been introduced by any of the amendments herein.

The dependent claims have been objected to for reciting "A method," instead of "The method." These claims have been amended as suggested by the Examiner, and the rejection is moot.

The claims have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.. The Examiner asserts that the written description does not support the scope of the claims with respect to the portions of the sigma^{70} subunit that may be used to practice the invention. This rejection is inappropriate and should be withdrawn.

The Examiner is treating the claimed invention as if it were per se "the sigma^{70} subunit or a portion thereof." However, the subunit or portion is recited as a component among several to be used in the claimed assay system. What is important and of relevance is the knowledge in the field that all bacterial sigma^{70} subunits contain an anti-sigma^{70} binding region. Thus, any assay mixture that includes a component containing this region would have the potential to be an effective mixture for

practicing the instantly claimed invention.

The Examiner has made several points with regard to what is considered to be a requisite number of examples and has asserted that the instant specification does not meet these requirements. In the first place, Applicants would disagree with this assessment on its face.

In addition to the consideration of how many specific examples are provided in the specification, it should be pointed out that the Examiner, in another rejection in the present Office Action (to be addressed later in this response), has cited the disclosure by the cited reference of Adelman et al. of a fusion protein containing the C-terminal 108 amino acids of the sigma^{70} subunit as one of the bases for leveling an anticipation rejection. Thus, the Examiner has herself recognized and acknowledged that there was additional information available to one of skill in the art as to what would be a portion containing the anti-sigma^{70} binding region.

Regardless of these considerations, the fact is that the Examiner has misapplied the written description criteria to the facts of the present case. As the Examiner would acknowledge, specific examples of "anti-sigma^{70}" factors, in particular the AsiA protein, have been identified and there are well known methods for monitoring the binding of a compound to the anti-sigma^{70} binding region. In fact, the Adelman, et al. disclosure

teaches a means "[T]o ensure that GSTσ(506) harbors the full site for AsiA binding..."; the very portion of Adelman cited by the Examiner provides this teaching. Thus, it would have been routine for Applicants at the time of the instant invention to test a given portion of the sigma^{70} subunit with, for example, the AsiA protein, to determine if that portion did indeed contain the anti-sigma^{70} binding region. Thus, the knowledge in the field at the time, when taken with the acknowledged disclosure in the instant specification, must be taken as confirmation that Applicants had possession of the invention at the time of filing.

Furthermore and perhaps most tellingly, the Examiner has made several statements in the Office Action that indicate a misunderstanding of the principles of the instantly claimed invention.

In the first place, the Examiner states that "[T]here is no guidance as to what portions can or cannot be used in the method being claimed. Thus, the resulting portion could result in a complexes [sic] not taught and enabled by the specification." Again, it is clearly set out in the specification and claims what portions can be used in the practice of the present invention; any portion of the sigma^{70} subunit comprising the anti-sigma^{70} binding region can be used.

The Examiner further states: "Moreover, the specification

fails to describe any other representative species by any identifying characteristics or properties other than having the anti-sigma binding region." This statement is ineffective as support for an assertion of lack of written description. It must be emphasized that the instantly claimed methods are based on the determination of competitive binding between a test compound and the AsiA protein to the sigma^{70} subunit; the subunit or portion thereof need have no other characteristic than containing the anti-sigma^{70} binding region for the claimed assay system to work.

Thirdly, the Examiner states that "[T]he specification does not contain any disclosure of the structure of all the mutants or variants of any portions within the scope of the claimed genus." The instant claims do not recite portions of the subunit which are "mutants or variants" in the sense meant by the Examiner. As must be clear from the instant specification, the "portions" of the sigma^{70} subunit to be used in the instant identification system are portions of the wild-type subunit which encompass the anti-sigma^{70} binding region. There are certainly no "mutations" contemplated in the present invention, nor are there any "variants," other than truncated versions of the sigma^{70} subunit, which truncated versions still encompass the anti-sigma^{70} binding region.

For all of the reasons set forth above, this rejection is

inappropriate and must be withdrawn. Withdrawal is respectfully requested.

The claims have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. In part a of the rejection, the Examiner asserts that the goal stated in the preamble is not commensurate with the subsequent method steps of the claim. The claim has been amended by the addition of an "identifying" step, and the rejection is moot. In part b of the rejection, the Examiner asserts that the phrase "a fusion protein of anti-sigma^{70} factor of bacteriophage T4" is unclear. This phrase has been replaced by the phrase "GST-AsiA fusion protein," and rejection is moot. The rejection of claim 5 in part c is moot, as the claim has been canceled.

The claims have also been rejected under 35 U.S.C. §112, second paragraph as being "incomplete for omitting essential steps…." In part a of the rejection, the Examiner asserts that there is no correlation step bridging the "identifying and determining" steps. The amendment herein of claim 1 in response to the indefiniteness rejection in section 4 of the Office Action, and discussed in the paragraph immediately above, also satisfactorily addresses this rejection. In part b of the rejection, the Examiner asserts that a step directed to the contacting of various of the components is necessary in claim 2, but lacking. Applicants disagree that any "clarification," at

least in the form of claim amendments, is required.

In the first place, claim 2 is dependent from claim 1 and therefore has all of the limitation recited in the base claim. Claim 1 clearly recites "contacting the sigma^{70} subunit... with a test compound and a... fusion protein." Furthermore, anyone of skill in the art would appreciate that the first antibody, when added, would contact the fusion protein against which it was generated and, similarly, that the second antibody, directed against the first antibody, would upon its addition contact said first antibody. Thus, it would be clear to the skilled person or anyone reading the instant application, that "adding" the various compounds as set forth in steps (ii), (iii) and (iv) is tantamount to contacting the molecules with each other as required to practice the claimed invention. No amendment of the claims is necessary, and the rejection should be withdrawn.

Claims 1 and 3-6 also stand rejected under 35 U.S.C. §102(a) as being anticipated by the cited journal article of Adelman et al. Applicants have amended claim 1 herein to more clearly and particularly recite the subject matter regarded as the invention. Support for the amendments in connection with the identity of the fusion protein and the means of producing it can be found in the specification on, for example, page 13, lines 10-16.

The Examiner cites an Adelman passage teaching the

GSTσ(506) fusion protein, which is comprised of the C-terminal 108 amino acids of sigma^{70} fused to GST. On the other hand, the fusion protein recited in the instant claims is one in which GST is fused to the AsiA protein. Furthermore, in describing the expression of the GSTσ(506) fusion protein, Adelman refers to the article of Dombroski et al., Cell 70: 501-512 (1992). As can be seen from page 509, column 2, lines 12-14 of Dombroski, the fusion protein was expressed in *E. coli*. On the other hand, as specified in the amended claims herein, the fusion protein is produced in a yeast system. It cannot be said that all the elements of the instantly claimed methods are taught by Adelman, and the anticipation rejection cannot be sustained. The Dombroski et al. reference is being made of record, and a copy provided, via an Information Disclosure Statement being submitted on the same date as this Amendment and Response.

The claims also stand rejected under 35 U.S.C. §102(b) as being anticipated by the cited article of Pahari et al. Again, Applicants have amended claim 1 herein to more clearly and particularly recite the subject matter regarded as the invention.

Particularly with regard to claim 1, the Examiner asserts that Pahari et al. teach, inter alia, a fusion protein of an anti-sigma^{70} factor of bacteriophage T4. The Pahari article has been studied and no indication of a teaching of such a fusion

protein was found. Even if it were true that Pahari provides such a teaching, this is not the GST-AsiA fusion protein recited as a component of the instantly claimed invention. Further along these lines, the AsiA protein is a part of the fusion-protein component of the present invention, whereas, as the Examiner acknowledges in the rejection, AsiA serves as the test compound in the study described by Pahari.

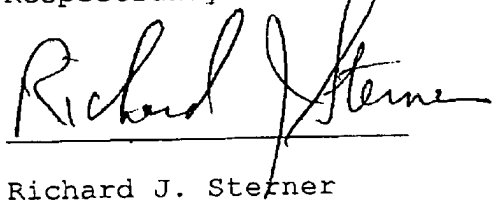
With regard to claim 2, the Examiner refers to Pahari Fig. 3 and asserts that Pahari teaches anti-sigma^{70} antibodies and anti-AsiA antibodies "as the first antibody" and a polyclonal antirabbit sigma^{70} antibody as "the second antibody." In the first place, the Examiner has misinterpreted what the figure legend says. It is clear from the legend that the "first antibody," is, if anything, the polyclonal antirabbit antibody and that the anti-sigma^{70} and anti-AsiA antibodies constitute the "second antibody." Furthermore and regardless, the first antibody of the present invention, as clearly recited in claim 2, is an antibody against the fusion protein, not an antibody against AsiA alone. The second antibody of the present invention is recited to be an antibody **against the first antibody**. Thus, the antibodies of the instant invention are not the antibodies taught by Pahari. Again, it cannot be said that all the elements of the present claims are taught by Pahari, and the anticipation rejection cannot be sustained.

In light of the amendments and arguments set forth herein, the objections to the claims and all of the rejections under 35 U.S.C. 112 have been properly addressed, and the claimed methods are patentable over the cited prior art. Reconsideration and allowance of the application with pending claims 1-4, 6 and 7 are respectfully requested. Should any other matters require attention prior to allowance, it is requested that the Examiner contact the undersigned.

No additional fees should be due in connection with this communication. However, should it be determined that an additional fee is due for any reason, the Commissioner is hereby authorized to charge it to Deposit Account No. 23-1703.

Dated: January 24, 2008

Respectfully submitted



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